IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
THIS DOCUMENT RELATES TO:	:	**MDL No. 3094**
	:	**Case No. 2:24-md-3094-KSM**
ALL ACTIONS/ALL CASES	:	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO PERMIT MARKETING DISCOVERY OR TO RECONSIDER ORDER PRECLUDING MARKETING DISCOVERY

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I. Introduction

Two of the cross-cutting issues this Court identified in CMO No. 18 are whether the Defendants' warning labels are "adequate" as a matter of law and whether federal law preempts Plaintiffs' failure to warn claims. The Court granted Defendants' request for early discovery and motion practice as to preemption and adequacy of the warnings and ordered the parties to jointly propose deadlines for regulatory and company discovery.[1] In a footnote, the Court cautioned the parties against pursuing discovery "into Defendants' marketing campaigns during early discovery on Issue 2." CMO 18 p. 10 n. 9. The preclusion of marketing discovery was not decided after a full development and submission of the arguments as to why so-called "marketing" discovery is relevant to the preemption and adequacy of the warnings issues. As such, Plaintiffs believe that there was limited opportunity for the Court to fully consider this issue of whether so-called marketing discovery is relevant to the issues that will be the subject of the Defendants' fast-tracked cross-cutting summary judgment motions, particularly with the unique and novel approaches to discovery and dispositive motion practice that were proposed by Defendants.

As to marketing discovery, the Court stated that "discovery into Defendants' marketing campaigns" is "best left until after the Court rules on whether as a matter of law, any Plaintiff may assert a claim for failure to warn based in whole or in part on a manufacturer's direct to

[1] Defendants' request regarding for such a sweeping and critical discovery restriction was not brought on by motion but by conference agenda item and subsequently filed short letter briefs that covered many significant issues. The briefs were simultaneously exchanged. There were several issues discussed in the 5-page letter briefs and the marketing discovery issue was subsumed by the broader litigation shaping issues and not even directly discussed in the briefs as something to be restricted. The push to preclude marketing discovery occurred orally during brief telephone conferences, which also included other issues. Thus, Plaintiffs' view is that the Court did not have an opportunity to fully and directly hear the Plaintiffs on this massive substantive discovery restriction.

consumer claim." CMO 18 p. 10 n. 9. Defendants have leveraged this language in taking extreme positions and flatly refusing to consider producing plainly discoverable information.[2] However, marketing discovery is not merely relevant to marketing claims made directly to consumers. Numerous courts have recognized that a pharmaceutical company can dilute or negate the warning in a label by concealing or downplaying a risk *to doctors or the medical community at large*. Further, courts have recognized that warning claims based upon marketing efforts are not preempted because no federal law requires pharmaceutical companies to conceal or downplay risks in their marketing efforts. Accordingly, Plaintiffs respectfully request that this Court issue an order permitting marketing discovery during this initial phase of discovery and direct the parties to meet and confer regarding any limitations of scope that Defendants think are appropriate and bring the scope issue to the Court, if necessary, following the meet and confer process and utilization of the Special Master.

Defendants' highly sophisticated marketing strategies seek to influence the medical information that is presented to the medical community at large—in medical journals, guidelines, continuing medical education, medical conferences and conventions and through medical organizations. For example, pharmaceutical companies such as Defendants often provide talking points for or strongly influence the content of talks presented by prestigious doctors to large groups of doctors about the risks and benefits of a drug. Pharmaceutical companies, like

[2] Plaintiffs Request for Production ("RFP") No. 23 seeks, *inter alia*, documents "sufficient to demonstrate" money paid by Lilly and Novo to groups such as the American Board of Obesity Medicine, the American Academy of Pediatrics, and the American Diabetes Association. Defendants stated that they refuse to negotiate any production relating to their funneling of money to these groups on the basis that such payments are "marketing." Defendants have taken the same position in connection with many such requests relating to their influence of the medical community's understanding of their drugs, including refusing to provide any information on payments to individuals who Lilly and Novo paid to speak to doctors relating to their drugs.

Defendants, also influence the medical community's knowledge about the risks and benefits of a drug through payments and communications with medical professionals who author medical literature or through financial support for medical organizations who create guidelines on the standard of care for the treatment of a condition through influence on continuing medical education content. Pharmaceutical companies may also edit or influence medical articles that discuss the risks and benefits of the drugs they sell.

In addition, marketing discovery regarding off-label promotion of the drugs for conditions beyond the FDA approved indication for each drug are squarely relevant to Defendants' affirmative preemption defense. To the extent Defendants promoted their drugs for off-label uses, FDA did not evaluate the risks and benefits of those off-label uses and would not have reviewed warnings relevant to those uses. Preemption arguments about those claims would fail.

The above-described marketing discovery is deeply relevant to the affirmative defense of federal preemption and any motion regarding the adequacy of Defendants' warnings. No issue should be considered or decided without the necessary record; and as to federal preemption and warning adequacy that record includes marketing evidence. Pharmaceutical marketing strategies often seek to downplay the risks of a drug while overemphasizing the benefits of a drug. Business plans, strategy documents, sales training guides, sales manager reviews from 'ride-alongs' with sales representatives, and an array of marketing materials are relevant to the company's knowledge of safety issues with their drugs *and efforts to hide those risks from regulatory authorities and healthcare providers*. Moreover, evidence that Defendants promoted their drugs for off-label uses, through business and marketing plans, branded and unbranded marketing pieces, KOL (key opinion leaders) training guides, meetings with outside scientific

advisors and other cross-functional medical and marketing activities would defeat any preemption argument, because the FDA would not have evaluated the risks of the drug for those off-label uses. These are not case specific issues. The marketing was national in scale and magnitude, and everything that occurred with regard to these drugs over the last several years is in some way tethered to the marketing.[3]

II. Standard

Plaintiffs' position is that the Court should view the instant motion not as reconsideration but as the first full hearing on this matter. However, if the Court views the matter as having been determined and an Order on the same issued, then Plaintiffs in the alternative move for reconsideration of the Court's prior Order precluding marketing discovery.

Federal Rule of Civil Procedure 54(b) provides that:

> [A]ny order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities."

Under Rule 54(b), "A district court is entitled to reconsider its interlocutory orders 'when it is consonant with justice to do so.'" *Alea N. Am. Ins. Co. v. Salem Masonry Co*., 301 F. App'x 119, 121 (3d Cir. 2008) (quoting *United States v. Jerry*, 487 F.2d 600, 605 (3d Cir. 1973)); *see also State Nat'l Ins. Co. v. Cnty. of Camden*, 824 F.3d 399, 406 & n.14 (3d Cir. 2016); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 493 (3d Cir. 2017) ("[I]nterlocutory orders ... remain open to trial court reconsideration, and do not constitute the law of the case.") (quoting *Perez-Ruiz v. Crespo-Guillen*, 25 F.3d 40, 42 (1st Cir. 1994)).

[3] It is certainly possible that there might be *some* marketing discovery that would not be relevant at this stage under the preemption and adequacy preliminary motions. Plaintiffs cannot conjure up now what that would be, but Defendants no doubt would have some views. If there is some limitation that is appropriate, then perhaps the parties could work with Special Master Stengel to sort that out together.

III. Marketing Discovery is Relevant

As multiple courts have held, a pharmaceutical company's marketing and promotional efforts are relevant to whether the company failed to provide an adequate warning. *See In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-MD-2244-K, 2017 WL 3841608, at *4 (N.D. Tex. June 28, 2017) ("This argument ignores the fact that the RCH email evidences Defendants' general marketing and sales culture, which, at the very least, is relevant to Plaintiffs' claims of Failure to Warn.");[4] *In re Depakote*, 87 F. Supp. 3d 916, 928 (S.D. Ill. 2015) (finding that marketing "evidence is relevant on the issue of what Abbott knew and when it knew about the scope of Depakote's birth defect risks and its proper use in women of childbearing years. This evidence may also be relevant to the content of the 1999 label if, as Plaintiffs suggest, they can show that Abbott's marketing strategy influenced its label."); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & PMF Prod. Liab. Litig.*, No. 3:09-CV-10012-DRH, 2011 WL 6740391, at *10 (S.D. Ill. Dec. 22, 2011) ("[E]vidence about sales goals is certainly relevant particularly when it may impact decision making regarding labeling. There is an inherent tension between the desire for profit and scientific decisions that suggest warnings that may well shrink the customer base because of cautionary tone stricken by the warnings."); *see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig*., 369 F.3d 293, 314 (3d Cir. 2004) ("[E]xcessive concern with the image and marketing of the diet drugs at the expense of making efforts toward determining whether they were safe could be probative as to whether [the manufacturer] breached a duty of care towards the plaintiffs.").

[4] *See also In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig*., No. 3:11-MD-2244-K, 2017 WL 6559765, at *4 (N.D. Tex. July 7, 2017) (finding that marketing deposition "topics are relevant [and] proportional"); *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig*., No. MDL 3:11-MD-2244-K, 2013 WL 2091715, at *2 (N.D. Tex. May 15, 2013) (compelling marketing discovery).

As explained below, marketing discovery is relevant both to the adequacy of a warning and to preemption. Notably, the scope of discovery is generally broad:

> Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1). However, "the court must limit the … extent of discovery otherwise … if it determines that … the proposed discovery is outside the scope permitted by Rule 26(b)(1)." Fed. R. Civ. P. 26(b)(2)(C)(iii).

Under Rule 26(b)(1), if the party seeking the discovery "demonstrates that the requested discovery is within the scope of permitted discovery, the burden then shifts to the opposing party to demonstrate that the requested discovery (i) does not fall within the scope of discovery contemplated by Rule 26(b)(1), or (ii) is not sufficiently relevant to justify the burden of producing the information." *Fed. Trade Comm'n v. Am. Future Sys., Inc.*, No. 2:20-CV-02266-JHS, 2023 WL 3559899, at *5 (E.D. Pa. Mar. 28, 2023) (citation omitted).[5] "Relevance is construed broadly to encompass any matter that could bear on, or that could reasonably lead to other matter that could bear on, any issue that is or may be in the case." *Fed. Trade Comm'n*, 2023 WL 3559899, at *5.[6]

[5] *See also First Niagara Risk Mgmt., Inc. v. Folino*, 317 F.R.D. 23, 28 (E.D. Pa. 2016); *United States v. AmerisourceBergen Corp.*, No. CV 22-5209, 2024 WL 3696471, at *2 (E.D. Pa. Aug. 7, 2024).

[6] *See also Fed. Nat'l Mortg. Ass'n v. SFR Invs. Pool 1, LLC*, No. 214CV02046JADPAL, 2016 WL 778368, at n.16 (D. Nev. Feb. 25, 2016) ("Despite the recent amendments to Rule 26, discovery relevance remains a broad concept.").

Here, as explained below, marketing discovery is relevant and important to determining the adequacy of Defendants' warning and to their preemption defense. Put simply, dispositive motion practice on issues of affirmative defenses of preemption and adequacy of warnings requires a thorough investigation of Defendants' unprecedented marketing practices. By way of example, Novo Nordisk paid U.S. medical professionals at least $25.8 million dollars over a decade in fees and expenses related to its weight-loss drugs, Saxenda and Wegovy.[7] These marketing practices introduce bias, can lead doctors to overlook alternative treatment options and can lead to overprescription and off-label usage. *See* Exhibit A, Wang et al., *Public Health Responsibilities in the Era of GLP-1 Receptor Agonists* (2024) pp. 1-2. Moreover, Defendants have not demonstrated that the discovery is burdensome.

A. Marketing discovery is relevant to the adequacy of a warning.

Even under the learned intermediary doctrine, Defendants' duty to warn is not limited to the label and includes their marketing efforts to the medical community. Plaintiffs need marketing discovery now because Defendants' marketing should be part of the inquiry into the adequacy of the label. Judge Rufe's *Avandia* order—which is cited in CMO No. 18 (at ¶ 10)—explains in detail why this discovery is necessary. *See* CMO 18 pp. 6-7. The *Avandia* court addressed whether GlaxoSmithKline's drug label was adequate as to the risk of congestive heart failure ("CHF"). The label warned that Avandia caused fluid retention, which can lead to or exacerbate CHF; that Avandia should be discontinued upon deterioration of cardiac status; that Avandia should be used cautiously in patients at risk for heart disease; and that incidents of CHF had been reported. *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 817 F. Supp. 2d 535, 537 (E.D. Pa. 2011). Based on those warnings, GSK sought judgment as a matter of law,

[7] https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/, last accessed September 6, 2024.

asserting that it had warned adequately about the risk of CHF. *Id.*

One of the plaintiffs' counter arguments claimed that GSK had "watered down the fluid retention warning through its reassuring marketing and media communications." *Id.* at 553. After reviewing all of the evidence, the court held that there was a question of fact regarding the adequacy of the warnings. Among other conclusions, Judge Rufe held that "a reasonable jury in a jurisdiction recognizing an overpromotion exception could conclude that GSK's efforts to dissociate edema from CHF diluted the effect of the 2001 warning about the relationship between edema and CHF." *Id.* at 555. The court also noted that, under Pennsylvania's learned intermediary doctrine, "a drug manufacturer may be held liable for inadequate warnings where marketing representations dilute the warnings of an otherwise adequate label." *Id.* at 555 n.108 (citing *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971), *overruled on other grounds by Kaczkowski v. Bolubasz*, 421 A.2d 1027 (Pa. 1980)).[8]

Pennsylvania is not unique, and it is widely recognized that a manufacturer can dilute or nullify a warning to doctors through overpromotion. For example, an MDL judge in Illinois, applying the laws of Utah and Tennessee, rejected an argument that a drug manufacturer's warnings were adequate on similar grounds. The court held that "[m]any states apply the overpromotion theory, under which a manufacturer can be liable for failure to warn even when the warnings were adequate if it engaged in an advertising campaign that in effect negated the

[8] *See also Incollingo*, 282 A.2d at 220 ("[W]hether or not the warnings on the cartons, labels and literature of Parke, Davis in use in the relevant years were adequate, and whether or not the printed words of warning were in effect cancelled out and rendered meaningless in the light of the sales effort made by the detail men, were questions properly for the jury."); *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984) (following *Incollingo*); *Stanton by Brooks v. Astra Pharm. Prod., Inc.*, 718 F.2d 553, 578 (3d Cir. 1983) (noting that, on remand, plaintiffs will be able to present evidence at trial "that Astra 'overpromoted' the drug"); *Stevens v. C. R. Bard, Inc.*, No. 17CV1388, 2018 WL 692097, at *3 (W.D. Pa. Feb. 2, 2018) (following *Incollingo* and *Baldino*).

warnings." *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2017 WL 1836435, at *16 (N.D. Ill. May 8, 2017). *See also, e.g.*, *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (applying North Carolina law and stating that "overpromotion of the drug may erode the effectiveness of otherwise adequate warnings"); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (holding that "an adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given"); *cf. Okuda v. Wyeth*, No. 1:04-CV-80 DN, 2012 WL 12337860, at *1 (D. Utah July 24, 2012) (recognizing the overpromotion theory but concluding that it was not supported by the evidence in that case) (applying Utah law); *Romero v. Wyeth LLC*, No. 1:03-CV-1367, 2012 WL 12547105, at *5 (E.D. Tex. May 30, 2012) (same, applying Texas law).[9]

[9] *See also Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 112 (Ky. 2008) ("This evidence showed that Sandoz repeatedly attempted to downplay or conceal the risks of Parlodel and intentionally undermined any existing warnings. This systematic approach to minimizing the risk posed by Parlodel rendered the various warnings that were available inadequate under the learned-intermediary doctrine."); *Brown v. Glaxo, Inc.*, 790 So. 2d 35, 40 (La. App. 2001) ("The jury could have reasonably concluded that Glaxo's verbal representations diluted or confused the connection between "alarming" chest pains and cardiac dangers."); *Proctor v. Davis*, 682 N.E.2d 1203, 1215 (Ill. App. 1997) ("The evidence convincingly supports the conclusion that Upjohn promoted, encouraged and advertised the off-label use of Depo–Medrol by providing financial and technical assistance to a limited number of members of the medical community without attempting to communicate to these physicians and the medical community at large the dangers and risks attendant to this use."); *Holley v. Burroughs Wellcome Co.*, 348 S.E.2d 772, 777 (N.C. 1986) ("His testimony that assuming Holley suffered from malignant hyperthermia, the failure of medical personnel to timely recognize and treat such condition was in part due to defendants' inadequate warnings and overpromotion, constitutes a forecast of competent evidence which, if believed by a jury, would establish the essential element of proximate cause in plaintiffs' negligence action."); *Lindquist v. Ayerst Lab'ys, Inc.*, 607 P.2d 1339, 1345 (Kan. 1980) (following *Stevens*, 507 P.2d at 61); *Whitley v. Cubberly*, 210 S.E.2d 289, 292 (N.C. App. 1974) (recognizing liability for "if over-promotion through a vigorous sales campaign should induce the medical profession in general, and in this case Dr. Cubberly in particular, to fail adequately to heed the warnings given.").

Overpromotion liability, which considers marketing to the medical community, is distinct from this Court's analysis on the issue of direct-to-consumer marketing discovery. The Court wrote that "the parties should refrain from pursuing discovery into Defendants' marketing campaigns during early discovery" on the question of label adequacy. CMO 18 at 10 n.9. The court considered the issue of direct-to-consumer marketing, where a plaintiff seeks to hold a defendant liable for statements or omissions in marketing materials created by the manufacturer and viewed by the plaintiff. *See* CMO 18 at 10 nn.8-9 (stating that questions about whether the court could look beyond the label due to direct-to-consumer advertising could be put off until after resolution of questions regarding the adequacy of the warning).

In other words, this Court rejected the need to consider claims that would operate **outside** of the learned intermediary doctrine. But while Plaintiffs do intend to pursue those claims, Defendants' overpromotion of the drugs at issue to the medical community—if proved—is relevant **within** the learned intermediary doctrine. The theory focuses on statements that downplay a product's risks to the medical community, thereby eroding or nullifying the impact of any warnings on the label. *See, e.g.*, *Salmon*, 520 F.3d at 1363 (holding that calendars sent to physicians promoting a drug precluded summary judgment, as reasonable jurors could infer "that the absence of a warning on an advertisement for the use of [the drug] was a form of overpromotion which nullified the effect of even a valid warning on the package"). While some of Defendants' marketing is public, discovery on this issue is critical, as some marketing goes directly to physicians—whether through written materials, through sales representatives, through presentations at conferences, or through other means not accessible to Plaintiffs' counsel.

A related point is that context always matters as to the adequacy of warnings. Simply using the words "nausea and vomiting" on a label does not discharge the Defendants' duty to

warn of the injuries suffered by the plaintiffs in this MDL. *See, e.g.*, *In re Avandia*, 817 F. Supp. 2d at 546 (holding that the laws of Pennsylvania, Texas, New York, and Florida vary semantically in how they describe the duty to warn, but that "each state requires that the label accurately and unambiguously convey the scope and nature of the risk, with sufficient specificity given the particular of the risk at issue"). Notably, following the first bellwether trial in the massive MDL over pelvic mesh products, the defendant argued that its label was adequate as a matter of law, given that the complications suffered by the plaintiff were listed on the warnings accompanying the medical device. The MDL court rejected that argument under Georgia law, holding that "it was for the jury to decide whether [the manufacturer] adequately warned Dr. Raybon about rates and severity of complications associated with the [product]." *Cisson v. C.R. Bard, Inc.*, No. 2:11-CV-00195, 2013 WL 5700513, at *7 (S.D.W. Va. Oct. 18, 2013), *aff'd sub nom. In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016).

In other words, the adequacy of the warnings is not just about the words being used, it is also about the message being conveyed. Here, Defendants' promotion of the drugs at issue to the medical community bears on whether the warnings on the label were adequate. If Defendants downplayed the risks of their drugs to physicians, then such representations likely dulled the effects of their (unembellished) warnings about nausea and vomiting. Such evidence is relevant to Plaintiffs' argument that Defendants' warnings were inadequate.

B. Marketing discovery is relevant to preemption.

This Court has also permitted Defendants' request for early motion practice and discovery into preemption. To demonstrate preemption, Defendants must present clear evidence that federal law prohibited them from taking different, non-negligent actions. *See Merck v. Albrecht*, 587 U.S. 299, 314 (2019); *Wyeth v. Levine*, 555 U.S. 555, 570 (2009); *In re Avandia*,

945 F.3d 749, 758 (3d Cir. 2019). In short, Defendants must show that it was "impossible" to comply with state negligence and product liability law. *Wyeth*, 555 U.S. at 572.

Initially, no federal law requires Defendants to make verbal or written communications with doctors or the medical community that are inconsistent with the label. Accordingly, as the court recognized in *In re Actos® (Pioglitazone) Prod. Liab. Litig.*, No. 6:11-MD-2299, 2014 WL 12776173, at *17 (W.D. La. Sept. 5, 2014), states can prohibit companies from negligently marketing their drugs. In *Actos*, the court rejected Lilly's preemption argument for its marketing activities, noting that the plaintiff presented evidence at trial that Lilly's marketing was inconsistent with the label. *Id.* at *17-18 & n. 147. *See also In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, No. 05-1699 CRB, 2006 WL 2374742, at *11 (N.D. Cal. Aug. 16, 2006) (addressing preemption) ("[T]here is nothing in the record from which the Court could conclude that the FDA has actually reviewed all of the submitted advertisements, let alone conclude that the FDA's review means that it has definitively determined that the advertisement was not misleading.").

Similarly, in *City & Cnty. of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 666 (N.D. Cal. 2020), the court held that federal law did not bar a claim that the defendants made communications to doctors and the medical community that were inconsistent with the label. As the court explained, "the City's claims are predicated on Defendants' promotion of the use of opioids far beyond what was contemplated in the approved label." *Id.* at 668 (addressing preemption).

Furthermore, in *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2017 WL 1836443, at *8 (N.D. Ill. May 8, 2017), the court rejected a preemption argument based upon off-label promotion. *See also Lempa v. Eon Labs,*

Inc., No. 18 C 3821, 2019 WL 1426011, at *4 (N.D. Ill. Mar. 29, 2019) (holding, like *TRT*, that off-label promotion claim is not preempted); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 994–95 (D. Ariz. 2013) (same).[10] As in these cases, Defendants' marketing and promotion of their drugs is relevant to the question of whether federal law preempts Plaintiffs' claims.

Moreover, the court in *Mahnke v. Bayer Corp*., No. 219CV07271RGKMAA, 2020 WL 2048622, at *5 (C.D. Cal. Mar. 10, 2020), held that the preemption question as to marketing efforts should be made on a full record after discovery. As in *Mahnke*, this Court should decide the preemption question on a full record, and a full record includes marketing discovery.

C. Defendants have not shown that the marketing discovery is not proportional.

As previously explained, where discovery is relevant, the objecting party bears the burden to prove that the discovery is not proportional. *Fed. Trade Comm'n v. Am. Future Sys., Inc.*, 2023 WL 3559899, at *5. Here, Defendants have not done so. The marketing discovery is proportional to Plaintiffs' needs as Defendants seek to persuade this Court to grant summary judgment against, if not every single Plaintiff in this multidistrict litigation, a substantial majority. Given the size of this litigation, the amount in controversy weighs heavily against limiting Plaintiffs' access to discovery. Defendants have not demonstrated that the marketing discovery will be unduly burdensome or costly, and it is clearly relevant.

IV. Conclusion

For these reasons, it is respectfully submitted that this Court should issue an order permitting marketing discovery, and directing the parties to meet and confer regarding any

[10] Plaintiffs do not bring claims for violating the FDCA, but rather for violating their state law obligations to adequately warn of risks and to not improperly promote off-label use of a prescription drug. As a result, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001), is no bar. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, 2017 WL 1836443, at *8; *Lempa*, 2019 WL 1426011, at *4; *Ramirez*, 961 F. Supp. 2d at 994-95.

limitations of scope that Defendants think is appropriate and to bring any scope issue(s) to the Court, if necessary, following the meet and confer process and utilization of the Special Master.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 6, 2024, I filed the foregoing motion with the Clerk of the Court using CM/ECF system. I also certify that the foregoing document is being served this day on all counsel of record via Case Management/Electronic Case Filing System ("CM/ECF").

/s/ Paul Pennock
Paul Pennock